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RAPID ETHICS REVIEW

CHILDHOOD CONSENT FOR COVID-19 VACCINATION

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On 13th September 2021, Public Health England recommended that children aged 12 to 17 should be offered a single dose of the Pfizer vaccine to protect against covid-19, following advice from Chief Medical Officer (CMO) for England, Chris Whitty. This recommendation was contrary to advice given by JCVI on 3rd September. According to the JCVI advice, although the health benefits of vaccinating children are marginally greater than the unknown harms from not vaccinating children below 16, the margin is too limited to recommend across the board vaccination in this age group at this stage.

The question of whether or not children should be offered vaccination against covid-19 raised significant ethical challenges. This is a rapid review looking retrospectively at these challenges, taking into account best interests, capacity to consent, vaccine mandates, and data governance issues.

OVERVIEW

- Whether children should be vaccinated turns on a range of factors, including age, capacity, the balance between vaccine safety and covid-related harm, data security.
- Since capacity varies in children and cannot be assumed at any particular age, this must be assessed on a case-by-case basis, acknowledging potential tensions with parental wishes.
- As with adult vaccination policy, questions over mandating vaccination are of particular ethical significance.
- There are significant uncertainties about current and future data security, sharing, and reuse, which will affect the balance of ethical benefits and risks in vaccinating children.

INTRODUCTION

Initial trial data (detailed below) indicated that the covid-19 vaccinations are highly effective in preventing severe covid-19 in adolescents, and that the vaccines are well tolerated in this age-group. While a number of countries (including the USA) approved the use of vaccines in children as young as 12 on the basis of this data, there was considerable debate about whether covid-19 vaccination is in a child's best interests. Despite the promising efficacy and safety data, children face a low mortality risk from covid-19, and there is still some uncertainty about the long-term safety profile of the vaccines in children. Indeed, the US Centers for Disease Control and Prevention (CDC) have investigated reports of myocarditis in young people following vaccination.

The prospect of vaccinating children against covid-19 also raised questions about informed consent requirements for medical treatment in treatment. For example: What should happen if the views of parents and children diverge? How can individual control over personal health data be secured in the transition from parental to personal consent? What weight should be given to the importance of vaccination, given that children are at low risk of harm from covid-19?

These questions are particularly challenging because the term 'child' covers an age range where capacity is developing and can vary extensively from one individual to another. In particular, it overlaps with adolescence, a transitional phase to adulthood, so while all individuals under age 18 may be regarded in law as children, the inability to give informed consent cannot be inferred from this fact alone.

Since the homogeneity implied by the label 'child' is not reflected in the capacity to give consent among children of even the same age, so deliberations about what constitutes ethical conduct with respect to their wishes is correspondingly non-uniform.

Given these complex interlocking concerns, in what follows we outline some of the key ethical and legal considerations at stake in questions about informed consent for childhood vaccination in the context of this disease.

IS VACCINATION IN A CHILD'S BEST INTERESTS?

One preliminary question is whether vaccination is in a child's best interests and if so, how certain we are of this.

In September 2021 Pfizer / Biontech announced trial data showing that their vaccine is 100% effective in for children aged 5-11, and that it is well-tolerated in and safe for use by this group. This followed similar findings for children aged 12-15 announced in March 2021. Moderna also released promising data in this regard.

However, although this data is promising, it is not in itself sufficient to determine that covid-19 vaccination is in a child's best interests. First, children face a very low risk of mortality or morbidity from covid-19. The risk of death from covid in children is approximately one in a million. Even if the vaccine is highly effective in children, it can only serve to diminish what is already a very small risk in the absence of vaccination. Second, there are still a number of uncertainties regarding the long-term safety profile of the vaccines in children. The Centre for Disease Control and Prevention reports that since April 2021, over a thousand cases of myocarditis and pericarditis, which is inflammation of the heart, have been reported following receipt of an mRNA covid-19 vaccine. The majority of these cases have been in adolescents.

Of course, it should also be noted that there are some uncertainties that speak in favour of vaccinating children. Despite their low mortality and morbidity risk from covid-19 in the short term, there is little data about whether infection poses longer-term risks to health in children, or about the incidence of 'long covid' in children. Related to this, although data suggests that the majority of infected children are either asymptomatic or experience only mild covid-19, there is some uncertainty about whether asymptomatic infections may pose longer-term risks to health. Notably, some of the vaccines that are currently authorised for use in children (such as the HPV vaccine) serve to protect children from known longer term risks (such as the development of cervical cancer). As we continue to gather data about the long-term effects of covid in children, the case for vaccination may grow stronger, depending on what those data reveal.

The balance of risks and benefits is also affected by whether or not children are otherwise healthy and free of underlying vulnerabilities. Much of the preceding analysis is implicitly based on an 'all other things being equal' approach to the question of whether children should or should not be vaccinated. However, in children with underlying comorbidities, or children from black and minority ethnic backgrounds there may be prudential reasons for vaccination in spite of the current lack of long term safety data, due to the higher risks faced by these children. As such, the ethical case for vaccinating children, at least in terms of direct immunological benefit, is not uniform and will turn in part on differences in risk status for specific children, even where data is suboptimal.

Indirect harms may also follow from decisions about whether or not to vaccinate children. For instance, there have been non-medical risks such as interruption to schooling, which is harmful to children, not only in terms of the impact on learning but also interpersonally and in relation to mental and physical health. Indeed, the CMO advised in favour of vaccination against JCVI's recommendation in part because this will help to reduce disruption to schooling (as well as in view of winter approaching, in which the infection rate is likely to spike). While children who test positive for covid-19 have had to take days off school to self-isolate, other children in close contact may also experience interruptions to their education if they are also required to self-isolate. Much here depends on the covid-19 policy adopted in schools. In early July, for example, under the school bubbling policy, all close contacts of a child testing positive for the virus were required to self-isolate.

Government statistics published on the 13th July indicate that around 800,000 children in state-funded schools did not attend school in the preceding week for covid-19 related reasons. This represents 11.2% of all such pupils (up from 8.5% the preceding week).

We return to the matter of vaccination as a condition of access to school in more detail below, but in any case, it is not yet clear whether vaccination against covid-19 is in a child's best interests. Indeed, based on the available risk data for children, on 3rd September JCVI recommended that vaccination should be offered to children no younger than age 16, other than those at high risk because of underlying health conditions, in which case vaccines may be offered to children age 12 and over. JCVI's judgement was that although health benefits from vaccination are marginally greater than the potential known harms, they consider the margin of benefit as too small to support universal vaccination of healthy 12 to 15 year olds at this time.

This qualified and limited recommendation reflects residual safety concerns for children, even in spite of a reasonable expectation of safety. It is therefore noteworthy in light of this that the government has decided not to take JCVI's advice, and instead to extend the offer of vaccination beneath age 16, to all children aged 12-15. Children in this group have been offered a single dose of vaccine, apart from those who have underlying health conditions, or who live with someone at elevated risk, who may receive the standard two doses.

Given the absence of consensus, further data are clearly necessary. However, there are significant challenges to obtaining the evidence necessary for establishing a comprehensive picture of the short and long term risks and benefits for children. The generation of such data depends on children being participants in the necessary paediatric trials. Trials involving children are typically carried out only after rigorous and extensive testing in adults. This poses a dilemma: the course of action which poses the least harm to children should be chosen, but the production of the data required to make such a choice may involve putting children at risk of harm. There is no straightforward resolution to this dilemma, but it is important to make explicit what is at stake in being sufficiently informed to develop and implement policies about whether children should or should not be offered vaccines.

Notwithstanding these challenges, it is likely that we will learn more about the long-term effects of vaccination and covid-19 in children, particularly as other countries have authorised the use of covid-19 vaccines in children. As such, we now turn to consider ethical issues regarding consent to covid-19 vaccination in children that arise in this younger cohort of children aged 12-15, given the government's decision to extend vaccine access to them.

CONSENT AND CAPACITY IN CHILDREN

Informed consent requirements in medicine are fundamentally grounded by the principle of respect for autonomy (Beauchamp and Childress, 2001). To give informed consent is to give an autonomous authorisation of a medical treatment, an authorisation that serves to waive rights (such as the right to bodily integrity) that would otherwise preclude the permissibility (and lawfulness) of a medical treatment.

On the standard understanding of autonomy in bioethics (Beauchamp and Childress, Ibid.), an autonomous authorisation of a medical treatment is one that is made:

1. intentionally
2. with sufficient understanding
3. in the absence of controlling influences that determine choice.

In order to autonomously authorise a medical treatment in this manner, an individual must have the various abilities that are necessary for making (and communicating) a decision in this manner. That is to say, a patient must have decision-making capacity to autonomously authorise a medical treatment.

In England and Wales, the Mental Capacity Act (2005) [MCA] applies to individuals over the age of 16. Section 3 (1) outlines the following four abilities as necessary for decision-making capacity:

a. The ability to understand information relevant to a decision
b. The ability to retain the information long enough to be able to make a decision
c. The ability to use of weigh that information as part of the process of making a decision
d. The ability to communicate their decision.

A further grounding principle of the MCA is that an individual must be assumed to have decision-making capacity, unless it is established that they lack capacity.

Informed consent requirements play a central role in the treatment of adults with decision-making capacity. Such individuals are largely afforded the legal authority to refuse medical treatment even when that treatment is in their best interests, and valid consent is typically deemed to be necessary for providing a medical treatment to such patients (including vaccination). There are some exceptions to this, as capacitious individuals suffering from mental disorders as defined by the Mental Health Act may lack the legal authority to refuse certain treatments (UK Government Mental Health Act 1983, Revised 2007).

One challenge regarding consent to vaccination in adults is determining whether a given adult has the decision-making capacity necessary to consent to or refuse vaccination. If an adult lacks capacity, then the decision about whether to vaccinate that individual will be determined by a best interests assessment of that treatment.

Yet, there are also challenges regarding consent to vaccination in adults who have been deemed to have decision-making capacity for that decision. One such challenge is determining whether the individual has made a decision to consent or refuse vaccination on the basis of sufficient understanding, and in the absence of controlling influences that would undermine the voluntariness of their decision.

Informed consent requirements in the treatment of children are more complex. That is because the ability to make autonomous decisions develops gradually over childhood. The older the young person is, the more likely they are to have the requisite ability to decide for themselves. However, it is not simply a question of age. Some younger adolescents may be more mature and able to make decisions, while some older adolescents may not.

There is no clear age-defined threshold where fully autonomous decision-making capacity is achieved; however, developmental neuroscience data, using brain development as a proxy for cognitive sophistication, may provide at least a heuristic for this. For example, Noroozi, Singh and Fazel (2018) write that although synaptic density increases from birth, it does not continue to do so indefinitely, beginning its decline before adulthood. As such, 'overall neurological maturation does not occur until mid to late adolescence', with this process 'typically completing around 24 years'. Similarly, while adolescence is closely associated with the onset of puberty, the age at which puberty actually begins can differ. As such, the age of a child alone can only suggest an approximation of their degree of capacity.

In the UK, the law distinguishes between adolescents of different ages:

The MCA applies to those between the age of 16-17, and they are assumed to have decision making capacity. This means that adolescents of 16 and above could consent to medical treatment on their own accord – without the permission of their parents being required.

Below the age of 16, the MCA does not apply. Children and adolescents under this age are not assumed to have the capacity to make their own treatment decisions (Wilkinson, Herring, and Savulescu, 2019).

Nonetheless, some children under the age of 16 who have demonstrated "sufficient maturity and intelligence to understand and consider the nature and risks of a proposed treatment, as well as any alternatives available" may be deemed to be 'Gillick competent' (Griffith, 2016) A child who is Gillick competent may have the legal authority to consent to certain treatments that are in their best interests.

The law is more complicated when it comes to young people refusing treatment. A Gillick competent child's refusal of treatment can be overridden by an adult with parental responsibility, if that treatment is in their best interests and necessary to prevent serious harm (Wilkinson, Herring, and Savulescu, Ibid.) That could also apply to adolescents aged 16-17 (we will note below that this is unlikely to be relevant to immunisation).

Conversely, if a child is *not* Gillick competent, then consent to treatment must be obtained from the adult with parental responsibility for that child, as outlined by the Children Act 1989 (Wilkinson, Herring, and Savulescu, Ibid.). This adult may consent to treatment that is deemed to be in a child's best interests, but their refusal of treatment that is in a child's best interests may be overridden by the Court of Protection.

Of course, the wishes of children who are not Gillick competent (and adults who lack decision-making capacity) are not irrelevant to the ethics of medical treatment decisions. Although such individuals cannot provide valid consent to (or refusal of) medical treatment, they may nonetheless express assent or dissent to treatment. Such assent and dissent is morally significant, even if it does not amount to a full blown autonomous authorisation or refusal of treatment that warrants legal

authority. First, the patient's own wishes may have an important role in determining whether a treatment is in the individual's best interests, not least because providing treatment to a dissenting patient may cause the individual considerable distress. Second, assent can have moral relevance because decision-making capacity is a range property; although it is treated as a binary threshold concept in the law, it is a property that is ultimately assigned on the basis of abilities that admit of degree. A process of obtaining assent to treatment from a patient lacking capacity enables the patient to have an input into the treatment decision that is commensurate with her capacities, even if her assent does not amount to an autonomous authorisation of treatment (Pugh, 2020).

VACCINATION AND GILLICK COMPETENCY

In the context of covid-19 vaccination, the practical legal significance of whether or not a child is Gillick competent turns substantially on the contentious question of whether vaccination is sufficiently in the child's best interests.

Notably, it can potentially be lawful to perform a medical treatment that is in the child's best interests (i) on a Gillick competent child who wishes to refuse it (ii) on a non-Gillick competent child whose adult with parental responsibility refuses to consent to it and (iii) on a Gillick competent child without parental consent. However, given the current degree of uncertainty about the risk/benefit profile of the covid-19 vaccinations in children, it is unlikely that these vaccines would qualify as being sufficiently in a child's interests to warrant vaccination in the absence of valid consent from either the child herself or the adult with parental responsibility.

Yet, it is unlikely that a vaccine that is clearly not in a child's best interests would be authorised for use in children, so we should assume that since vaccines are being rolled out to them there are reliable grounds, backed up by evidence, for thinking that children would, on balance, benefit from vaccination.

Nonetheless, when a treatment decision concerns an intervention with less certain benefits, there are strong reasons to require a higher degree of certainty in our assessments of an individual's competence to make that decision (Pugh, Ibid. p. 196). The greater our uncertainty about whether vaccination is in a child's best interests, the more important it is to ensure that the child really has understood what is at stake in the decision they are making if they consent to vaccination.

Of course, it might be argued that even if vaccination is not clearly in the child's own best interests, there are nonetheless strong reasons to vaccinate children because of the indirect protective effect that this would have for others. Even if they are at low risk from the virus, children can nevertheless be vectors of transmission and spread the virus to more vulnerable population. This, as noted above, will be of particular significance during the winter months. Notably though, this justification is not grounded in the best interests of the child herself, and there is currently no legal basis for deploying such an argument to justify vaccinating a child (or adult) lacking capacity in the law.

MOVING FORWARD – FAIR ACCESS AND MANDATES?

Assuming that vaccination against covid-19 is sufficiently in a child's interests, then we face a range of ethical issues that have been raised by the roll-out of vaccinations in the adult population.

First, when vaccines are licensed for use in children, it is important to ensure fair access for all children. The vaccination programme has already revealed communities who are harder to reach and factors which compromise equal ease of access for all. The ethical significance of ensuring that all who want to be vaccinated can access vaccines is no less pressing in children just because they tend to be at lower risk of harm from covid-19 than older people. As such, what counts as ensuring that vaccination policy for children is fair must take into account structural factors which might lead to unequal access as well as the decision-making calculus involved with weighing up the short and long term benefits and risks of the vaccines themselves in terms of personal safety alone.

The permissibility of potentially mandating covid-19 vaccination as a condition of school entry may also arise following the licensing of vaccines for use in children (Gostin, Shaw, and Salmon, 2021). Indeed, some countries already mandate other vaccines for school entry (Savulescu, Giubilin, and Danchin, 2021), and covid-19 vaccination is already a requirement of certain professions (such as care home staff in England). Although such policies involve a degree of

coercive pressure that may undermine the autonomy of those subject to the requirement, some scholars have argued that they can be a necessary and proportionate element of a public health responses to the covid-19 pandemic (Bradfield and Giubilini, 2021).

However, the uncertainty of the benefits of vaccination in children, and the extent of their contribution to viral transmission within schools (Ismail et al, 2021) raise significant concerns about the potential necessity and proportionality of a measure mandating covid-19 vaccination for school entry.

DATA COLLECTION, USE, STORAGE, AND RE-USE

Although consent to a vaccination itself is a pressing moral concern, vaccinating children inevitably involves the collection of personal health data, as it does with adults. Given risks of data breaches, and the transition from childhood to adulthood and the implied transferral of autonomy to make decisions from parent to offspring that this represents, a proper treatment of the ethical ramifications of consent in children must include consideration of data ethical issues.

Questions over how data is collected, stored, shared, and may be re-used raise a different set of challenges for informed consent. Given the unprecedented nature of this pandemic, a prima facie concern is that it is unclear what the long-term storage, linkage, security, and privacy implications of this data usage will be, beyond the immediate conditions of lockdown and disruption of normal life. This is problematic, as valid consent requires a sufficient understanding of the act to which one is consenting. Furthermore, clarity about these aspects of data collection is required for reliable and trustworthy governance of health data collected in the course of the pandemic.

Data collected about children in the course of vaccination will be stored beyond the point at which they reach adulthood and are legally entitled to make their own decisions about disclosure of their own health information. In view of the unpredictable nature of the pandemic and its unfolding, it is hard to make accurate long-term predictions about how data might be used, shared, with whom and for what purposes. For example, in its report on the Coronavirus Act, the UK Parliament Human Rights Committee stipulates that '*the use of emergency procedures must be limited to what is absolutely necessary*'. However, the scope of what is meant by 'absolutely necessary' is open to debate. Similarly, it states that '*Disruption to our normal way of life and human rights are sometimes necessary in order to lead the country through any significant emergency, but this must always be done in a way that is proportionate and justifiable*'. Here, 'justifiability' and 'proportionality' are also contestable in scope. In general, emergency conditions, can be appealed to in defence of not following processes which might otherwise delay action, in virtue of being unusual events where normal rules do not necessarily apply. As such, there might be some reasonable concern about the acceptability of unusual data management practices, where such practices are argued to be commensurate with the exceptional nature of the circumstances.

Optimising the conditions of consent turns in part on transparency about what will happen to data collected. However, the unpredictability of the pandemic and its long-term effects may preclude certainty, and this may limit the extent to which consent can be genuinely informed. This is a risk not only for children, but for consent to vaccination in adults as well, so it is a general challenge to autonomous decision-making in the covid-19 context.

One way to mitigate the risk of unconsented data use may be to apply the mechanism of broad consent, in which the terms of consent are explicit that the data may be re-used for as yet unspecified purposes and the individual will not be recontacted on any of these subsequent occasions. Although this would not entirely discharge the concern outlined above about the exploitation of emergency conditions being used to justify unreasonable data management practices, it may go some way to maintaining the ethical integrity of consent, by ensuring that individuals are at least aware that their information may be shared and re-used before providing it.

There is evidence that concerns such as those outlined above have been recognised at the governmental level. For example, Public Health England's covid-19 surveillance in schoolchildren programme, which aims to monitor infection and antibodies in children and understand how children spread the disease, states clear conditions of data collection, handling, use, and re-use. In particular, PHE states that it will destroy all identifiable data at the end of the study, and anonymised data will be destroyed three years after the end of the study, in mitigation of some of the kinds of concerns we identify, albeit not in the context of vaccination specifically.

Of course, just because governmental or regulatory bodies observe stringent conditions of data security, it cannot be assumed that this will be the case with

any institution that handles data about an individual's vaccination status. This is ethically significant because of the risks to privacy. If one provides one's data on the condition that it will be held securely, then one is nominally harmed if this condition is not satisfied and the data is used in ways for which consent has not been given. The harm may become more serious depending on who has access to the data and the purposes for which they wish to use it. Moreover, analysis in Bloomberg Businessweek points out that although biometric tracking of vaccination status can ensure that a large proportion of the world's population develops immunity to covid-19, the complexity of these arrangements across the world make significant data leakage inevitable. Given the reasons why ethical concerns are amplified in the context of children, this represents a significant risk of harm both now and in the future.

There may be factors that will mitigate risks about disclosure of vaccination status to some extent. For example, the International Association of Privacy Professionals reports a judgement made by the Future of Privacy Forum that, in practice, data-related risks about vaccination status are limited. Unlike medical records, which will contain numerous data points that could compromise individual privacy, a covid-19 immunity need only contain proof of vaccination status, and nothing else. Nonetheless, the risks associated with recording, storing, handling, and sharing information about vaccination are amplified in the context of children in educational settings, for the reasons outlined above.

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About this review

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About the UK Pandemic Ethics Accelerator

The UK Ethics Accelerator is a UKRI/AHRC-funded initiative that brings UK ethics research expertise to bear on the multiple, ongoing ethical challenges arising during a pandemic emergency. We provide rapid evidence, guidance, and critical analysis to decision-makers across science, medicine, government, and public health. We also facilitate public stakeholder deliberation around key ethical challenges.